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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590 10/10/2002  
Engene C Rzucidlo  
Greenberg Traurig  
885 Third Avenue  
New York, NY 10022

EXAMINER

BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/786,853

Applicant(s)

OLIVER ET AL.

Examiner

Rachel M. Bennett

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

The examiner acknowledges receipt of IDS filed 7/02/01. A second first action on the merits is set forth below. Preliminary Amendment A (filed 3/9/01) has been entered (10/7/02). Claims 1-8 are pending.

#### ***Specification***

1. Claims 1-8 are objected to because of the following informalities: Article 34 Amendment comprising claims 1-8 has replaced original claims 1-9. However the Amended Sheets appear to be faxed copies and are not clear. The examiner requests a clean copy of claims 1-8 for the record.

2. The use of the trademark Costar® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-8 are indefinite because Applicants do not clearly define “substantially” in the claims. Claims 1-8 are indefinite because Applicants do not clearly define “sufficiently large to preserve the original architecture of the natural tissue”. Clarification is requested.

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5. The term "pasty" in claim 8 is a relative term which renders the claim indefinite. The term "pasty" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 5, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace et al. (Collagen Corp - EP 0251695).

Wallace discloses an injectable suspensions of biomaterials, such as cross-linked collagen, that contain a biocompatible fluid lubricant, such as glycogen or maltose. The inclusion of the lubricant significantly improves the intrusion of the suspension into soft tissue (see abstract). Example 4 discloses cross-linked collagen with glycerol or maltose. Claims 1-3 disclose an injectable implant composition for soft tissue augmentation comprising an aqueous suspension of a particulate biomaterial and sufficient amount of a biocompatible fluid lubricant, wherein the particulate biomaterial is fibrillar cross-linked collagen, having diameters in the range of about 1 to 20 microns. Therefore, these claims are anticipated.

8. Claims 1-3, 5-8 rejected under 35 U.S.C. 102(b) as being anticipated by Berg et al. (US 4837285).

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Berg discloses collagen-based compositions for augmenting soft tissue, wound dressings, implants, injectable formulations or other drug delivery systems, comprising resorbable collagen matrix beads (see abstract). The collagen, which is free from foreign materials and is completely resorbable by a patient's body, is in the form of a cross-linked material. The beads have a particle size of from about 100 to 4000 microns, preferably about 300 to 500 microns, and the porosities such that the collagenous material comprises up to about 30% of the total bead volume (see col. 3 lines 10-26). Pharmaceutically acceptable carriers are disclosed in col. 4, lines 46-54. Specifically, when employed in subcutaneously injectable formulations, the collagen matrix is suitably dispersed in a sterile aqueous dispersion glycerol (see col. 5). Therefore, these claims are anticipated.

9. Claims 1, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Janzen et al. (US 5523291).

Janzen discloses and injectable implant compositions for soft tissue augmentation comprising elastin and collagen and a biocompatible carrier. The injectable implant is derived from the *ligamentum nuchae* which has been treated to remove non-collagenous and non-elastinuous proteins. Therefore, these claims are anticipated.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 309-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett  
October 7, 2002

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600